

FORM PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No.: DHI-03864	Serial No.: 09/539,735
INFORMATION STATEMENT BY APPLICANT (Use Several Sheets If Necessary) (37 CFR § 1.98(b))				Applicant: James L. Brown	
				Filing Date: 03/30/00	Group Art Unit: 1644



U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patente	Class	Subclass	Filing Date
PN	1	4,609,622	9/2/86	Kohn <i>et al.</i>			
↓	2	5,071,773	12/10/91	Evans <i>et al.</i>			
↓	3	5,401,629	3/28/95	Harpold <i>et al.</i>			
↓	4	5,436,128	7/25/95	Harpold <i>et al.</i>			

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

PN	5	Botero and Brown (1998) "Bioassay of thyrotropin receptor antibodies with Chinese hamster ovary cells transfected with recombinant human thyrotropin receptor: Clinical utility in children and adolescents with Graves disease," <i>J. Pediatr.</i> 132:612-618
↓	6	Federman in <i>Scientific American Medicine</i> , Scientific American, New York, NY, Dale and Federman (eds.), 1997, Chptr. 3, Section I, pp. 2-22
↓	7	Baldet <i>et al.</i> (1987) "Thyroid stimulating antibody: an index of thyroid stimulation in Graves' disease?" <i>Acta Endocrinol. (Copenh)</i> 116:7-12
↓	8	Rapoport <i>et al.</i> (1984) "Clinical Experience with a Human Thyroid Cell Bioassay for Thyroid-Stimulating Immunoglobulin," <i>J. Clin. Endocrinol. Metabol.</i> 58:332-338
↓	9	Yokoyama <i>et al.</i> (1987) "Heterogeneity of Graves' Immunoglobulin G: comparison of Thyrotropin Receptor Antibodies in Serum and in Culture Supernatants of Lymphocytes Transformed by Epstein-Barr Virus Infection," <i>J. Clin. Endocrinol. Metabol.</i> 64:215-218
↓	10	McKenzie and Zakaria (1989) "Clinical Review 3, The Clinical Use of Thyrotropin Receptor Antibody Measurements," <i>J. Clin. Endocrinol. Metabol.</i> 69:1093-1096
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↓	12	Bidey <i>et al.</i> (1985) "Characterization of thyroid-stimulating immunoglobulin-induced cyclic AMP accumulation in the rat thyroid cell strain FRTL-5: potentiation by forskolin and calibration against reference preparations of thyrotrophin," <i>J. Endocrinol.</i> 105:7-15
↓	13	Michelangeli <i>et al.</i> (1994) "Measurement of thyroid stimulating immunoglobulins in a new cell line transfected with a functional human TSH receptor (JPO9 cells), compared with an assay using FRTL-5 cells," <i>Clin. Endocrinol.</i> 40:645-652
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↓	15	Vitti <i>et al.</i> (1993) "Detection of Thyroid-Stimulating Antibody Using Chinese Hamster Ovary Cells Transfected with Cloned Human Thyrotropin Receptor," <i>J. Clin. Endocrinol. Metabol.</i> 76:499-503
↓	16	Kosugi <i>et al.</i> (1989) "Mechanisms by Which Low Salt Condition Increases Sensitivity of Thyroid Stimulating Antibody Assay," <i>Endocrinol.</i> 125:410-417
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↓	18	Maniatis <i>et al.</i> (1987) "Regulation of Inducible and Tissue-Specific Gene Expression," <i>Science</i> 236:1237-1245
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↓	20	Dijkema <i>et al.</i> (1985) "Cloning and expression of the chromosomal immune interferon gene of the rat," <i>EMBO J.</i> 4:761-767
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Examiner: *Patricia J. Nor* Date Considered: *10/22/01*

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)					
<i>PN</i> <i>✓</i>	27	Sambrook <i>et al.</i> , Molecular Cloning: A Laboratory Manual, 2nd ed., Cold Spring Harbor Laboratory Press, New York [1989], pp.16.9-16.15			
	28	Chiovato <i>et al.</i> (1994) "Detection of antibodies blocking thyrotropin effect using Chinese hamster ovary cells transfected with the cloned human TSH receptor," <i>J. Endocrinol. Invest.</i> 71:809-816			
	29	Di Cerbo <i>et al.</i> (1999) "Graves' Immunoglobulins Activate Phospholipase A ₂ by Recognizing Specific Epitopes on Thyrotropin Receptor," <i>J. Clin. Endocrinol. Metabol.</i> 84:3283			
	30	Guyton (1981) "The Thyroid Hormones," in <i>Textbook of Medical Physiology</i> , Sixth Edition, W.B. Saunders Company			
	31	Hartmann <i>et al.</i> (1993) "The Effects of PEG on Second Antibody Immunoprecipitation and Its Use in Immunoassay," <i>J. Immuno.</i> 14:241-266			
	32	Inui <i>et al.</i> (1998) "Increase of Thyroid Stimulating Activity in Graves' Immunoglobulin-G by High Polyethylene Glycol Concentrations Using Porcine Thyroid Cell Assay," <i>Thyroid</i> 8:319-325			
	33	Jacobson <i>et al.</i> (1997) "Epidemiology and Estimated Population Burden of Selected Autoimmune Diseases in the United States," <i>Clin. Immunol. and Immunop.</i> 83:223-243			
	34	Loos <i>et al.</i> (1995) "Enhanced cAMP accumulation by the human thyrotropin receptor variant with the Pro52Thr substitution in the extracellular domain," <i>Eur. J. Biochem.</i> 232:62 (Abstract)			
	35	Ludgate <i>et al.</i> (1990) "Use of the recombinant human thyrotropin receptor (TSH-R) expressed in mammalian cell lines to assay TSH-R autoantibodies," <i>Mol. and Cell. Endocrinol.</i> 73:R13-R18			
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	39	Murakami <i>et al.</i> (1995) "Clinical usefulness of thyroid-stimulating antibody measurement using Chinese hamster ovary cells expressing human thyrotropin receptors," <i>Euro. J. Endocrinol.</i> 133:80-86			
	40	Ochi <i>et al.</i> (1999) "Clinical Usefulness of TSAb Assay with High Polyethylene Glycol Concentrations," <i>Horm. Res.</i> 51:142-149			
	41	Perret <i>et al.</i> (1990) "Stable Expression of the Human TSH Receptor in CHO Cells and Characterization of Differentially Expressing Clones," <i>Biochem. Biophys. Res. Comm.</i> 171:1044-1050			
	42	Persani <i>et al.</i> (1993) "Measurement of cAMP accumulation in Chinese hamster ovary cells transfected with the recombinant human TSH receptor (CHO-R): a new bioassay for human thyrotropin," <i>J. Endocrinol. Invest.</i> 16:511-519			
	43	Roitt <i>et al.</i> (1998) <i>Immunology</i> , Fifth Edition, Mosby International Ltd., pp 371-380			
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	46	Vitti <i>et al.</i> (1988) "Measurement of TSAb directly in serum using FRTL-5 Cells," <i>J. Endocrinol. Invest.</i> 11:313-317			
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	48	Watson <i>et al.</i> (1998) "A new chemiluminescent assay for the rapid detection of thyroid stimulating antibodies in Graves' disease," <i>Clin. Endo.</i> 49:577-581			
	<i>PN</i> <i>✓</i>	49	Yamashiro <i>et al.</i> (1999) "Mechanism of the Augmentative Effect of High Polyethylene Glycol (PEG) Concentrations on the Thyroid Stimulating Activity in TSAB-IgG Using a Porcine Thyroid Cell Assay," <i>Endocrine Research</i> 25:67-75		
	Examiner:	<i>Patricia J. Norz</i>		Date Considered:	<i>10/22/01</i>
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OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)					
(P.N.)	50	FAQ Information: FAQ on Graves' Disease (1999) http://www.geocities.com/Athens/3626/graves.html			
(PN)	51	FAQ about Graves' Disease (1999) http://www.ngdf.org/faq.htm			
Examiner:	<i>Patricia J-Nel</i>		Date Considered: 10/22/01		
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PN	1	5,814,461	9/29/98	Bergmann <i>et al.</i>	435	7.1	8/18/94
<p style="text-align: right;">RECEIVED SEP 13 2001 TECH CENTER 1600/2900</p>							
FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS							
	Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
						Yes	No
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)							
PN	2	Morgenthaler <i>et al.</i> , "Application of a bioassay with CHO cells for the routine detection of stimulating and blocking autoantibodies to the TSH-receptor," <i>Horm. Metab. Res.</i> 30:162-168 [1998]					
Examiner:	<i>Patrich J. Nolan</i>			Date Considered:		<i>10/22/01</i>	
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